

REMARKS

Reconsideration of the present application is respectfully requested.

Claims 37-42 are added herein. Claims 1, 3-5, 7, 10, 13, 14, 18, 19, 20, 22 and 24-36 have been canceled. Claims 2, 6, 8, 9, 11, 12, 15, 16, 17, 21 and 23 are amended herein. Claim 37 is a new independent claim. Claims 38-42 depend from claim 37. In fact, all claims now depend from claim 37, either directly or through an intervening dependent claim. Claim 37 recites a control means for controlling the filtration/back filtration supply means, which provides control over the extracting of blood, the filtration and purification of same, and the return of same to the patient. This feature is discussed below in detail. Claims 38-42 provide additional features related to controller functions.

Support for the claims as amended herein can be found throughout the specification. Claim 37 finds support, for example, in the paragraph commencing at page 24 line 3, and from Figs. 1, 2, 3, and 4. The control means finds support in the paragraph commencing at page 25 line 18, in the paragraph commencing at page 27 line 5, and from the text at page 35 line 7 to page 36 line 13. The original claims also support new claim 37.

The drawings have been objected to for reasons related to the failure to properly identify components 7, 17, and 18 as shown in Figs. 1 and 3. In this paper, the specification paragraphs commencing at page 24 line 3 and page 27 line

5 have been amended to address this oversight. Support for identifying 17 and 18 as the one puncture needle comes from the paragraph commencing at page 4 line 19, and from the paragraph commencing at page 33 line 7. Support for identifying 7 as the control means comes from the paragraph commencing at page 27 line 5. It is submitted that the amendments made herein cure the drawing objections concerning these elements.

Further, claims concerning element 8 have been canceled. Thus, it is submitted that this removes the drawing correction requirement stemming from this matter.

It is submitted that the amendments to the specification and claims that are made herein do not add new matter.

Claims 1-36 are rejected under 35 U.S.C. § 112 paragraph 2 for matters relating to formalities. It is submitted that the amendments made herein address these issues. Of note, claim 1 has been canceled.

Claims 1-32 and 34-36 are rejected under 35 U.S.C. § 103 (a) as unpatentable over JP -6-114102A in view of Chevallet. Claim 33 is rejected on the aforementioned combination, and further in view of Ohta et al. or Davidner. It is submitted that these rejections are moot, and no longer apply, in view of the submission of claims 37-42 herein.

As indicated, claims 37-42 recite in part a hemodiafiltration apparatus including a control means for controlling the operations of the filtration/back-filtration fluid supply means and the blood pump. Not only does the recitation of the control means more particularly point out the inventive aspects of the application, it is submitted that this feature distinguishes the claimed subject matter from the prior art.

Claim 37 indicates that the filtration/back-filtration fluid supply means and the blood pump provide flow and are capable of operating in normal and opposite directions. The control means controls the direction of fluid supply, the fluid supply rate, and the time fluid is supplied by the fluid supply means. Claim 37 defines the control means in terms of details of the control on the filtration/back-filtration fluid supply means. Claims 38-42 additionally define the control means in terms of details of the control of the blood pump, and further control over the filtration/back-filtration fluid supply means.

As indicated in claim 37, the control means of the apparatus of the subject application controls the filtration/back-filtration fluid supply means to repeatedly perform a series of operations in a cycle over a predetermined number of times.

The first control provided for the control means operates the filtration/back-filtration fluid supply means in a direction opposite to the supply

delivery means for supplying the dialysis fluid for a preset, predetermined period of time. Through this function, blood is extracted from a body of the patient.

In a subsequent second control, the control means stops the filtration/back-filtration fluid supply means for a preset, predetermined period of time. Through this operation, the extracted blood is purified. The blood is purified through diffusion by counterflow with the dialysis fluid.

In the subsequent third control, the control means operates the filtration/back-filtration fluid supply means in the same direction as the supply delivery means for supplying the dialysis fluid for a preset, predetermined period of time that is shorter than the period of time for the extraction of blood. Through this operation, purified blood is reinfused into the body of the patient.

In the subsequent fourth control, the control means stops the filtration/back-filtration fluid supply means for a preset, predetermined period of time. Through this operation, blood in the blood circuit is purified. This blood purification is also performed through diffusion by counterflow with the dialysis fluid.

The control means of the apparatus of the subject application repeats the cycle of controlling the filtration/back-filtration fluid supply means for a preset, predetermined number of times. Specifically, after blood in the blood circuit is

purified through the fourth control, the control means repeats the cycle, commencing with the first control identified above.

The advantages provided by the claimed apparatus flow from the control operations. In the second control, where the control means stops the filtration/back-filtration fluid supply means for a predetermined period of time, blood is purified through diffusion by counterflow with the dialysis fluid that is introduced to the hemodialyzer. It is submitted that this step contributes to blood purification. If the blood purification by diffusion is not performed, blood of a suspect purity is returned to the body of the patient, which is the problem encountered with conventional single-needle hemodiafiltration.

Further, the fourth control, in which the control means stops the filtration/back-filtration fluid supply means for a predetermined period of time, during which time blood is purified through diffusion by counterflow with the dialysis fluid that is introduced to the hemodialyzer, also leads to blood purification efficiency. That is, if the fourth control is not performed, then the extraction of blood occurs right after the reinfusion of blood. This is the case with conventional single-needle hemodiafiltration, where blood returned after purification is quite possibly subjected to immediate extraction, so that only blood around the puncture needle undergoes purification. This is another problem with conventional single-needle hemodiafiltration that the present invention

overcomes. In addition, the advantage produced by the fourth control insures that the control means does not transition to the extraction of blood immediately after the reinfusion of blood, thereby eliminating a dead space phenomenon in which the fluid in the membrane of the hemodialyzer is cycled back and forth.

Thus, in view of the excellent results attained by the claimed subject matter, and the prior art deficiencies related to the control means now recited in the claims, it is respectfully submitted that the rejections are traversed. Importantly, none of JP 6-114102A, Chevallet, Ohta et al. or Davidner disclose or suggest a hemodiafiltration apparatus having a control means that can perform the functions of controlling the flow of the fluids through the apparatus. Accordingly the rejections are believed to be traversed.

REQUEST FOR EXTENSION OF TIME

Applicants respectfully request a three month extension of time for responding to the Office Action. The fee of \$1110.00 for the extension is provided for in the charge authorization presented in the PTO Form 2038, Credit Card Payment form, provided herewith.

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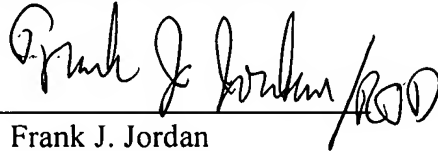
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is hereby authorized to charge any fee(s) or fee(s) deficiency or credit any excess payment to Deposit Account No. 10-1250.

In light of the foregoing, the application is now believed to be in proper form
for allowance of all claims and notice to that effect is earnestly solicited.

Respectfully submitted,

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